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EXAMINER

SQUIRES, ELIZA A

ART UNIT

PAPER NUMBER

3626

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03/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/614,079	Applicant(s) SWENSON ET AL.	
	Examiner Eliza Squires	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Amendment filed 12 January 2009 has been entered. Claims 1-27 remain pending in the application. Claims 28-29 have been added. Claims 1-29 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1 6, 9, 10, 12-13, and 28** rejected under 35 U.S.C. 103(a) as being unpatentable over *McConnell* in view of *Brown*.

4. **As to claim 1**, *Brown* discloses a method of collecting and testing data from a plurality of patient point of care locations, the method comprising:

receiving by a central device sample data from at least one sample testing device at a patient point of care location, said sample testing device is adapted to engage an analytical device and provide said sample data, said central device adapted to maintain at least one database (see figures 1, 2, and 9, and abstract also column 1, line 6 to column 2, line 6);

updating said database by the central device, said updating based upon at least one of said received sample data, analytical device and patient identifier information, and provide said database to a network server (column 9 lines 66-67 and column 10 lines 1-7 and figure 1).

While *Brown* discloses the use of an analytical device connected to the remote apparatus he does not specifically state that the device is a sample cartridge, *McConnell* discloses a sample cartridge (page 57, 2nd column).

Brown also does not explicitly disclose receiving cartridge identifier information or tagging data with patient identifier information.

McConnell discloses controlling said central device to receive cartridge identifier information from said sample testing device and tagging data with patient identifier information (*McConnell* page 58, lower half, 4th bullet). Examiner notes that the device of *McConnell* processes tests and downloads the results to a server through a docking station. *McConnell* is not designed for anonymous testing, therefore the data must be tagged with a patient identifier and cartridge identifier information in order to have any utility in a database. *McConnell* 4th bullet page 58 recites “laser bar-code scanning for all data entry- saves time, eliminates manual entry errors”. It is therefore implicit in the reference that patient identifier and cartridge identifier information are read by the barcode reader.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to expedite the collection of sample analysis results utilizing a remote system in a patient point of care system.

5. **As to claim 6**, see the discussion of claim 1. *Brown* further discloses a method of collecting and testing data from a plurality of patient point of care locations, further comprising:

controlling said central device to communicate data to said patient identifier information label as at least one data packet communicated from said central device via a second wireless communication module (figures 1 and 9).

6. **As to claim 9**, see the discussion of claim 1, however *Brown* does not explicitly disclose that the input is incorporated with the sample testing device. *McConnell* discloses, a method of

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collecting and testing data from a plurality of patient point of care locations, wherein said data input device is incorporated with said sample testing device (page 58, bottom half 4th bullet).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to save time and reduce errors in identifying patient information within a point of care device.

7. **As to claim 10**, see the discussion of claim 1 however, *Brown* does not explicitly disclose that the input device is incorporated with the central device. *McConnell* discloses a method of collecting and testing data from a plurality of patient point of care locations, wherein said data input device is incorporated with said central device (page 58, bottom half 3rd bullet).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to obtain patient records at a point of care location.

8. **With respect to claim 12**, See the discussion of claim 1; however, *Brown* does not explicitly disclose a system configuration inclusive of a contamination field. *McConnell* discloses a method of collecting and testing data from a plurality of patient point of care, wherein said testing device comprises at least one of a hand-held analytical device and stand-alone computer workstation, said testing device located within a contamination field about a patient at a patient point of care location (page 57).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to provide point of care laboratory analysis to improve efficiency and quality of patient care.

9. **With respect to claim 13**, see the discussion of claim 1, however, *Brown* does not explicitly disclose a system configuration inclusive of a contamination field. *McConnell* further

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discloses a method of collecting and testing data from a plurality of patient point of care locations, wherein said central device comprises at least one of a hand-held analytical device and stand-alone computer workstation, said central device located beyond a contamination field about a patient at a patient point of care location (Page 59, bottom half, 1st and 3rd bullet).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* to provide a centralized database for a group of such devices for increased patient privacy and improved organization of patient files for ease of use by medical personnel.

10. **As to claim 28**, see the discussion of claim 1, additionally, *McConnell* discloses a method of collecting and testing data from a plurality of patient point of care locations wherein said testing device comprises a hand-held analytical device (*McConnell* page 1 wherein “a blood analyzer...can be small, lightweight handheld analyzers”, said testing device located within a contamination field about a patient at a patient point of care location (*McConnell* wherein the contamination field is at a patients bedside), wherein said central device comprises a hand-held analytical device (*McConnell* page 58 and 59 wherein a stand alone computer workstation is a “docking station”) said central device located beyond the contamination field about the patient (the docking station is not at the patients bedside).

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11. **Claims 2-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Brown* in view of *McConnell* in further view of U.S. Patent Application Publication 2001/0051766 to *Gazdzinski*.

12. **As to claim 2**, see the discussion of claim 1, however the prior art does not explicitly disclose utilizing a wireless network. *Gazdzinski* discloses a method of collecting and testing data from a plurality of patient point of care locations, further comprising:

controlling said sample testing device to communicate said sample data to said central device as at least one data packet communicated from said sample testing device via a first wireless communication module (see page 19 paragraph [0216] where a sample testing device is a capsule endoscope).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* in order to utilize wireless communication to transmit testing data in order to reduce cost and minimize infrastructure.

13. **As to claim 3**, see the discussion of claims 1 and 2. Additionally, *Gazdzinski* further discloses a method of collecting and testing data from a plurality of patient point of care locations, further comprising:

controlling said sample testing device to communicate said sample data in a multiplexed format, said format including at least one of a time-division multiple access (TDMA) format, code-division multiple access (CDMA) format, and frequency-division multiple access (FDMA) format (page 19 paragraph [0219]).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* to utilize wireless communication including radio frequency format to obtain multiple data in order to reduce cost and minimize infrastructure.

14. **As to claim 4**, see the discussion of claim 1 above. Additionally *Gazdzinski* further discloses a method of collecting and testing data from a plurality of patient point of care locations, further comprising:

controlling said central device to receive said sample data from a plurality of sample testing devices simultaneously via a second wireless communication module (page 19 paragraph [0216]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* in order to allow for multiple patients to be sampled at one time saving time and expediting treatment.

15. **As to claim 5**, see the discussion of claim 1 above. Additionally, *Gazdzinski* further discloses a method of collecting and testing data from a plurality of patient point of care locations, further comprising:

controlling said central device to communicate data to said sample testing device at least one data packet communicated from said central device via a second wireless communication module (page 20 paragraph [0223]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* in order to allow two way communications between the central database and the remote device.

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16. **Claims 7-8, 14-15, 20-24, 26-27, and 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Brown* in view of *McConnell* and U.S. Patent Application 2003/0140928 to *Bui et al.*

17. **As to claim 7**, see the discussion of claim 1 and 6, however the prior art does not explicitly disclose a radio frequency identifier label. *Bui* discloses a method of collecting and testing data from a plurality of patient point of care locations, wherein said patient identifier information label is a radio frequency identification label (page 2 paragraph [0022]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Bui* in order to utilize encoded forms of data to add increased privacy protection and reduce medical errors in the processing of test samples.

18. **As to claim 8**, see the discussion of claim 1. Additionally, *Bui* discloses a method of collecting and testing data from a plurality of patient point of care locations, wherein said data input device is at least one of a bar code reader and a radio frequency identification reader (page 3 and 4, paragraph [0031]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Bui* in order to utilize encoded forms of data to add increased privacy protection and reduce medical errors in the processing of test samples.

19. **As to claim 14**, *Brown* discloses a system, adapted to collect and test data at a patient point of care location from a point located beyond a contamination radius about a patient using modular components to create a point of care network, the system comprising:

an analytical device, adapted to engage a sample testing device for testing a collected sample at a patient point of care location, said sample cartridge including a cartridge identifier

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mechanism, adapted to provide cartridge identifier information (see figures 1, 2, and 9, abstract, and column 5 lines 35-39);

a central device, adapted to receive sample data from said sample testing device at a patient point of care location, said central device being further adapted to maintain at least one database and to update said database based upon at least one of said cartridge identifier information, patient identifier information, and received sample data, and to provide said database to a network server (column 9 lines 66-67 and column 10 lines 1-7 and figure 1).

While *Brown* discloses the use of a monitoring device connected to the remote apparatus he does not specifically state that the device is a sample cartridge, *McConnell* discloses a sample cartridge (page 57, 2nd column).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to expedite the collection of sample analysis utilizing a remote system in a medical environment.

Brown also does not explicitly disclose a patient identifier label. *Bui* discloses a patient identifier label, adapted to provide patient identifier information (paragraph [022])

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Bui* in order to utilize encoded forms of data to add increased privacy protection and reduce medical errors in the processing of test samples.

20. **As to claim 15**, see the discussion of claim 14, however, *Brown* does not explicitly disclose a patient identifier label. *Bui* further discloses a system wherein:

said central device is further adapted to tag said received sample data with said patient identifier label information (paragraph [022]).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Bui* in order to utilize encoded forms of data to add increased privacy protection and reduce medical errors in the processing of test samples.

21. **As to claim 20**, see the discussion of claim 14, However, *Brown* does not explicitly disclose a patient identifier label or its use. *Bui* discloses a system wherein said central device is adapted to communicate data to said patient identifier information label as at least one data packet communicated from said central device via a second wireless communication module (paragraph [022]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Bui* in order to utilize encoded forms of data to add increased privacy protection and reduce medical errors in the processing of test samples.

22. **With respect to claim 21**, see the discussion of claim 14, however prior art does not explicitly disclose a radio frequency identification label. *Bui* discloses a system wherein said patient identifier information label is a radio frequency identification label (page 2 paragraph [0022]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Bui* in order to utilize encoded forms of data to add increased privacy protection and reduce medical errors in the processing of test samples.

23. **With respect to claim 22**, see the discussion of claim 14. Additionally, *Bui* further discloses a system, further comprising a data input device for communicating the patient identifier information to said central device, wherein the data input device is at least one of a bar code reader and a radio frequency identification label (page 3 and 4 paragraph [0031]).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Bui* in order to utilize encoded forms of data to add increased privacy protection and reduce medical errors in the processing of test samples.

24. **With respect to claim 23**, see the discussion of claim 14, however, *Brown* does not explicitly disclose that the input device is incorporated with the sample testing device.

McConnell discloses a system, wherein said data input device is incorporated with said sample testing device (page 58, bottom half 4th bullet).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to save time and reduce errors in identifying patient information within a point of care device.

25. **As to claim 24**, see the discussion of claim 14, however, *Brown* does not explicitly disclose that the data input device is incorporated with the sample testing device. *McConnell* further discloses a system, wherein said data input device is incorporated with said sample testing device (page 58, bottom half 3rd bullet).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to obtain patient records at a point of care location.

26. **As to claim 26**, see the discussion of claim 14, however, *Brown* does not explicitly disclose a system configuration inclusive of a contamination field. *McConnell* discloses a system, wherein said testing device comprises at least one of a hand-held analytical device and stand-alone computer workstation, said testing device located within a contamination field about a patient at a patient point of care location (page 57).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to provide point of care laboratory analysis to improve efficiency and quality of patient care.

27. **With respect to claim 27**, see the discussion of claim 14, however, *Brown* does not explicitly disclose a system configuration inclusive of a contamination field. *McConnell* discloses a system, wherein said central device comprises at least one of a hand-held analytical device and stand-alone computer workstation, said central device located beyond a contamination field about a patient at a patient point of care location (Page 59, bottom half, 1st bullet).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* to provide a centralized database for a group of such devices for increased patient privacy and improved organization of patient files for ease of use by medical personnel.

28. **As to claim 29**, see the discussion of claim 14, additionally, *McConnell* discloses a system of collecting and testing data from a plurality of patient point of care locations wherein said testing device comprises a hand-held analytical device (*McConnell* page 1 wherein “a blood analyzer...can be small, lightweight handheld analyzers”, said testing device located within a contamination field about a patient at a patient point of care location (*McConnell* wherein the contamination field is at a patients bedside), wherein said central device comprises a hand-held analytical device (*McConnell* page 58 and 59 wherein a stand alone computer workstation is a “docking station”) said central device located beyond the contamination field about the patient (the docking station is not at the patients bedside).

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29. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over *Brown* in view of *McConnell* in further view of the *I-Stat* website retrieved for the date 4/2/2003 via site <http://web.archive.org/web/20030402092614/www.istat.com/products/>.

30. **As to claim 11**, see the discussion of claim 1, however prior art does not explicitly disclose the type of blood tests to be performed. *I-Stat* discloses
A method of collecting and testing data from a plurality of patient point of care locations,
wherein said sample data comprises pH, pCO₂, pO₂, pC1, pNO₃, Na⁺, Ca⁺⁺, K⁺, hematocrit
and glucose levels in said sample (page 1 and 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *I-Stat* in order to provide a multiplicity of blood sample tests to be conducted at once in order to further expedite and improve patient treatment.

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31. **Claim 25** is rejected under 35 U.S.C. 103(a) as being unpatentable over *Brown* in view of *McConnell*, *Bui*, and *I-Stat*.

32. **As to claim 25**, see the discussion of claim 14, however prior art does not specifically disclose what blood tests are to be preformed. *I-Stat* discloses a system, wherein said sample data comprises pH, pCO₂, pO₂, pC1, pNO₃, Na⁺, Ca⁺⁺, K⁺, hematocrit and glucose levels in said sample (page 1 and 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *I-Stat* in order to provide a multiplicity of blood sample tests to be conducted at once in order to further expedite and improve patient treatment.

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33. **Claims 16-19**, are rejected under 35 U.S.C. 103(a) as being unpatentable over *Brown* in view of *McConnell*, *Bui et al.*, and *Gazdzinski*.

34. **As to claim 16**, see the discussion of claim 14, however prior art does not explicitly disclose a wireless system. *Gazdzinski* discloses a system, wherein:

said sample testing device is adapted to communicate said sample data to said central device as at least one data packet communicated from said sample testing device via a first wireless communication module (see page 19 paragraph [0216] where a sample testing device is a capsule endoscope).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* in order to utilize wireless communication to transmit testing data in order to reduce cost and minimize infrastructure.

35. **As to claim 17**, see the discussion of claim 14 and 15. Additionally, *Gazdzinski* further discloses a system, wherein:

said sample testing device is adapted to communicate said sample data in a multiplexed format, said format including at least one of a time-division multiple access (TDMA) format, code-division multiple access (CDMA) format, and frequency-division multiple access (FDMA) format (page 19 paragraph [0219]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* to utilize wireless communication including radio frequency format to obtain multiple data in order to reduce cost and minimize infrastructure.

36. **As to claim 18**, see the discussion of claim 14. Additionally, *Gazdzinski* further discloses a system, wherein:

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said central device is adapted to receive said sample data from a plurality of sample testing devices simultaneously via a second wireless communication module (page 19 paragraph [0216]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* in order to allow for multiple patients to be sampled at one time saving time and expediting treatment.

37. **As to claim 19**, see the discussion of claim 14. Additionally, *Gazdzinski* discloses a system, wherein said central device is adapted to communicate data to said sample testing device as at least one data packet communicated from said central device via a second wireless communication module (page 20 paragraph [0223]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* in order to allow two way communications between the central database and the remote device.

Response to Arguments

38. Applicant's arguments filed 20 October 2008 have been fully considered but they are not persuasive.

39. The rejections under U.S.C 112 second paragraph have been withdrawn in light of Applicant's amendment to claim 22.

40. Regarding the rejection under 35 U.S.C. 103 Applicant argues on page 9 that *McConnell* fails to disclose "controlling said central device to tag said received sample data with a patient identifier label information, said patient identifier label information communicated to said central device via a data input device".

41. There is no special definition provided in the claims or the specification for the terms control or tag. Examiner defines control as "the power to direct or determine" and tag as "a label associated with something for the purpose of identification". *McConnell* teaches controlling said central device to tag said received sample data with a patient identifier label information ("automatic downloading...to the LIS/HIS" and "laser bar-code scanning for all data entry" therefore the server and the LIS/HIS label the received information with patient identifiers), said patient identifier label information communicated to said central device via a data input device (the barcode reader). *McConnell* is not designed for anonymous testing, therefore the data must be tagged with a patient identifier and cartridge identifier information in order to have any utility in a database. *McConnell* 4th bullet page 58 recites "laser bar-code scanning for all data entry-saves time, eliminates manual entry errors". It is therefore implicit in the reference that patient identifier and cartridge identifier information are read by the barcode reader. Examiner further directs Applicant to the attached website for the "MediSense Precision PCx" taught in the

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McConnell reference; the reference teaches that the laser barcode scanner is for “data entry of information such as patient ID, operator ID, and test strip information which eliminates manual entry errors”. It is then inherent in the *McConnell* reference that the “MediSense Precision PCx” facilitates the tagging of this information.

42. Applicant argues on page 9 and 10 that *McConnell* does not provide “the concept or goal of providing a sample testing environment in which the sample testing device (ordinarily contaminated after use) is not removed from an already contaminated area”. It is unclear if Applicant is arguing a claim limitation or an asserted advantage. This is not part of any claim limitation, however should it be amended to include such a limitation, *McConnell* also suggests that “home patients could perform tests themselves” (page 57), also *Brown* similarly teaches remote monitoring where, for example, the glucose meter, never leaves the patients remote location (column 1 and 2).

43. Applicant further argues on page 9-11 that “replacing the monitoring devices of *Brown* with the portable devices of *McConnell* does not expedite sample collection or sample analysis results”. However one of ordinary skill in the art would have easily and immediately recognized that there would be numerous reasons for combining the two references including using a streamlined analysis of test specimens as well as its automated data entry features as taught by *McConnell* with the remote monitoring and database management features of *Brown* in order to reduce entry errors, hasten processing time for testing fluid by using a portable sample collection device requiring minimal fluid to obtain results, as well as reducing spread of infectious diseases by remotely providing fluid sample processing.

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44. Applicant further argues on page 11 that *McConnell* teaches away from a combination of the references “due to the fact the human charged with acquiring biological specimen data is free to enter and exit the contamination field with the point-of-care testing device.” *McConnell* does not criticize, discredit, or otherwise discourage the solution claimed, therefore *McConnell* does not teach away from the combination. See MPEP 2143.

45. Applicant argues on page 11 that *Brown* and *McConnell* fail to disclose “the location dichotomy with respect to the testing device and the central device embodied in claims 28 and 29”. These claims were newly added to the application, however, as discussed above, the server (central device) and the hand held device (especially when used in home care) in *McConnell* as well as the remote monitoring device and the database of *Brown* are located in separate locations relative to the patient meeting the requirement of the newly added claims.

The rejections are maintained.

Conclusion

46. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliza Squires whose telephone number is (571)270-7052. The examiner can normally be reached on Monday through Friday 8 am - 4 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. S./

Examiner, Art Unit 3626

3/23/09

/C. Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626